BOX Patent App

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Homan, et al.	Art Unit: 1724
Serial No: 09/177,902	Examiner: Ivars C. Cintins
Filed: 10/23/98	Paper No:
For: METHOD AND APPARATUS FOR PACKED COLUMN SEPARATIONS AND PURIFICATIONS	File No: E-1658
	Date: August 21, 2003

AFFIDAVIT

I, Brian Dockendorff, do hereby declare and state as follows:

From about October of 1996 until about June of 1999, I served as a research assistant in the Chemistry Department at the University of Washington (UW) under the direction of Professor Ruzicka. During my time at UW, I gained significant experience working with movable, solid rod valve members as those are described in the background section of the specification of the above captioned patent application (solid rods). During this time, I helped develop a miniaturized and fully automated solid phase extraction system using solid rods and based on sequential injection. I perfected the electrical and mechanical systems as well as edited software for computer interface, and applied this system to the extraction of Theophylline from a complex solution. During my time at the University, I participated in the following presentations and publications:

UW UNDERGRADUATE RESEARCH SYMPOSIUM
Invited to give a talk and present a poster at the first annual research meeting (April 1998)

INT'L CONFERENCE ON FLOW INJECTION ANALYSIS AND 32ND SEMI-ANNUAL MEETING OF THE JAPANESE ASSOCIATION FOR FIA
Selected by UW College of Arts and Sciences Divisional Sciences Dean to give a talk and present a poster (August 1998)

Dockendorff, B.; Holman, D, A.; Christian, G, D.; Ruzicka, J. Automated solid phase extraction of theophylline by sequential injection on renewable column. Anal. Commun. 1998, 35, 357-359.

Since June of 2000, I have been employed as a science and engineering associate at the Pacific Northwest National Laboratory (PNNL), Richland Washington. While serving in this capacity, I have participated in the development of a generic automated pathogen detection platform for use in clinical and non-clinical settings. During this project, I worked to advance chemistries, specifically PCR, SDA, bead capture and detection methodologies necessary for pathogen detection. The system includes the use and automation of a two bead capture technique, the magnetic capture cell and the rotating rod described in the above captioned US Patent Application.

The objectives of this project required that these chemistries be integrated with an easy to use electronics platform consisting of fluidic components and a microcomputer control system. This approach would be employed to carry out an automated routine designed to collect, process and detect from a sample specific pathogens without operator assistance. To that end, I assisted in designing the layout for, and helping to coordinate the building of a flexible automated Microfluidic System. Moreover, to allow for full automation, I designed and wrote *Fluidics System Software* for controlling Pumps, Valves, Detectors and Peltier PCR devices associated with these systems. As a result of this work, I have co-authored the following published manuscripts:

> Bruckner-Lea CJ, Tsukuda T, Dockendorff BP, Follansbee JC, Kingsley MT, Ocampo CF, Stults JR, and Chandler DP. 2001 "Renewable Microcolumns for Automated DNA Purification and Flow-through Amplification: From Sediment Samples through PCR." *Analytica Chimica Acta* . PNNL-SA-34985, Pacific Northwest National Laboratory, Richland, WA.
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> Bruckner-Lea CJ, Ackerman EJ, Dockendorff BP, Holman DA, Kim J, and Grate JW. 2001 "Renewable Surface Biosensors with Optical Detection ." In *Electrochemical Society Symposium Proceedings, 2001* PNNL-SA-34650, Pacific Northwest National Laboratory, Richland, WA.
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> Bruckner-Lea CJ, Ackerman EJ, Dockendorff BP, Holman DA, Kim J, and Grate JW. 2001 "Renewable Surface Biosensors With Optical Detection." In *Chemical and Biological Sensors and Analytical Methods* PNNL-SA-34465, Pacific Northwest National Laboratory, Richland, WA.

As a result of my work with both types of devices, and my general familiarity with this field of technology and technological development, I can offer the following observations.

1) Those having ordinary skill in the art of using and building microfluidic systems were very aware of the drawbacks and disadvantages inherent in the solid rod type systems described in the background section of the specification of the above captioned patent application (solid rods).

2) There is an inherent conflict in the design of the solid rods. On the one hand, tight tolerances are desired to prevent leakage. To accomplish tight tolerances requires the use of powerful solenoids and springs to drive in and out of the block. However, the use of such powerful solenoids and springs creates a tendency for the block to experience unacceptable wear and lose the tolerances necessary to trap particles, resulting in in unacceptable leakage. If, on the other hand, the solid rods are connected to less powerful springs and solenoids, they have a tendency to get stuck in an open or closed position. The end result is that the designer of solid rod systems is forced into making tradeoffs that will result in one or another type of failure within the solid rod system.

3) During my time in Professor Ruzicka's laboratory, I had extensive experience working with the solid rod type systems described in the background section of the specification of the above captioned patent application. I recently reviewed my laboratory record books to refresh my recollection of my experience working with these systems. I further had the opportunity to review laboratory records compiled at the Pacific Northwest National Laboratory (PNNL) for experiments utilizing the same solid rod systems. These records confirm that the experience at PNNL was substantially the same as my own experience at the University of Washington. As shown in the laboratory records, the solid rod systems fail with remarkable frequency, typically every other week when used every day in standard analytical experiments. For example, PNNL record books confirm three failures on a single system between January 27, 1999 and February 1, 1999. My own records reveal a minimum of four major failures requiring the system be re-built between October 18, 1996 and July 1, 1997. My recollection is that in addition to these major failures, recalibration of the solid rod systems was required on almost a weekly basis.

4) In contrast, once we transitioned to the rotating rod systems described and claimed in the above captioned patent application, the failures essentially stopped. A rotating rod system was in place at my laboratory on July 2000 when I began working at PNNL. This rotating rod system has been used continuously by myself and my fellow scientists ever since. My responsibilities include the maintenance of this system, and its repair in the event of failure. Fortunately, for the entire time, from July 2000 to the present, this system has not failed a single time.

5) My direct experience with these two systems over the course of the past 6 years has thus provided me with first hand knowledge allowing a direct comparison with the two systems, the salient points of which are recited above. Stated simply, the drawbacks and disadvantages inherent in the prior art solid rod type systems created significant incentives for alternative systems that would overcome these drawbacks and disadvantages, and those having ordinary skill in the art were very aware of these incentives. Despite the incentive for alternative systems that would overcome these drawbacks and disadvantages of these prior art solid rod systems, to my knowledge, none among those having ordinary skill in the art were able to conceive or reduce to practice any effective system for overcoming these disadvantages, until the rotating rod concept described in the above captioned patent application was conceived. The rotating rod concept described in the above captioned patent application thus fulfilled a long felt need among those having ordinary skill in the art for alternative systems that would overcome these drawbacks and disadvantages inherent in the prior art solid rod systems.

Upon penalty of perjury, by affixing my signature below, I hereby declare that the forgoing is true on this 21th day of August, 2003.

8-21-03

Brian Dockendorff